AUG 9 2000

D. 510K SUMMARY OF SAFETY & EFFECTIVENESS

This summary of 510K safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR807.92.

The assigned 510K number is: K000574

APPLICANT INFORMATION:

WR Medical Electronics Co.
123 North Second Street
Stillwater, MN 55082 USA
Tel: 651-430-1200
Fax: 651-439-9733
Attn: Patrick J. Anderson, President

DEVICE INFORMATION:

Trade Name: To Be Determined

Common Name: Iontophoretic Drug Delivery Electrode
Iontophoretic Electrode (active)

EQUIVALENT DEVICE:

Predicate Device No. 1: *iontophoretic electrodes furnished as a part of the device Model 2900 or MD-1,* R.A. Fisher Co. (PREAMENDMENT with information found in K895365 for later device)

Predicate Device No. 2: *Model RH800 electrode*, Iomed Inc., 1290 West 2320 South, Suite A, Salt Lake City, UT 84119 USA. (K914621)

Predicate Device No. 3: *Model RH805 electrode,* Iomed Inc., 1290 West 2320 South, Suite A, Salt Lake City, UT 84119 USA.. (K914264)

Predicate Device No. 4: *Meditrode electrode,* Life-Tech Inc., 4235 Greenbriar Drive, Stafford, TX 77477 USA.(K882554)

Predicate Device No. 5: *Dupel electrode, Empi.Inc.,* 599 Cardigan Road, St. Paul, MN 55126 USA. (K896703)

Predicate Device No. 6: *Dupel Iontophoretic Lead Wire Adaptor,* Empi.Inc., 599 Cardigan Road, St. Paul, MN 55126 USA. (K991991)

DEVICE DESCRIPTION:

The Iontophoretic Drug Delivery Electrode is a simple chamber designed to hold ionic solutions for the purpose

of iontophoretic delivery inot human skin as an alternative to hypodermic injection. See Statement of Indications.

INTENDED USE:

The Iontophoretic Drug Delivery Electrode is to be used with any FDA cleared iontophoretic stimulating device for the local administration of any FDA cleared ionic drug solution into the body for medical purposes as an alternative to hypodermic injection.

COMPARISON TO PREDICATE DEVICE:

Predicate devices Nos. 1,2,3,4 and 5 are all identical to the WR Medical Iontophoretic Electrode in that they are used to contain a fixed amount of drug to be delivered by iontophoresis. See comparison tables 1 and 2 below. Predicate device No. 6 is identical to the WR Medical Iontophoretic Electrode in that both are designed to be used with any commercially available iontophoretic stimulating device and are labeled as such.

Predicate devices Nos. 1,2,3,4, and 5 differ slightly in their measurements and volume capacity. See comparison tables 1 and 2 below. Predicate device No. 6 is a lead-wire adaptor, whereas the subject of this 510K is an electrode; but Predicate No. 6 is labeled the same as the WR Medical Iontophoretic Electrode in that both are designed to be used with any commercially available iontophoretic stimulating device and are labeled as such.

The use of the WR-produced Iontophoretic Electrode on a human does not effect the body any differently than the use of the predicate devices on humans; nor does the use of the WR-produced Iontophoretic Electrode raise any new questions of safety or effectiveness. From a technology point of view, the WR-produced Iontophoretic Electrode operates in exactly the same fashion as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 9 2000

Mr. Patrick J. Anderson
President
WR Medical Electronics Company
123 North Second Street
Stillwater, Minnesota 55082

Re: K000574
Device Name: Iontophoretic Electrode(active)
Regulatory Class: III
Product Code: EGJ
Dated: May 16, 2000
Received: May 18, 2000

Dear Mr. Anderson

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the devices as described below. This substantially equivalent decision applies to indications for the administration of soluble salts and other drugs into the body for medical purposes. You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Our substantially equivalent decision does not apply to any specific drugs. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

As you are aware, iontophoresis devices that are intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses, if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, were classified into Class II. An iontophoresis device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes other than those specified for class II devices is classified into Class III (21 CFR 890.5525). We published our strategy for calling for premarket approval (PMA) applications in the enclosed Federal Register, dated May 6, 1994, and the enclosed memorandum, dated April 19, 1994.

If you have any questions regarding this letter, you may contact:

Kevin Lee, M. D.
Division of General and Restorative Device
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850
Tel (301) 594-1296

This letter immediately will allow you to begin marketing your devices as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and permits your devices to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for question on the promotion and advertising, please contact the Office of Compliance at (301) 594-4639. Other general information on your toll free responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its number (800) 638-2041 or (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M. D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K00-0574

DEVICE NAME: Iontophoretic Drug Delivery Electrode, Iontophoretic

INDICATIONS FOR USE:

This device is a device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes.

(CFR 890.5525b)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use
(Optional Format 1-

Donna R. Vachner.
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000574